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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-12-0016; NOP-12-07PR]

RIN 0581-AD27

National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances (Crops and Processing).

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the U.S. Department of Agriculture's (USDA's) National List of Allowed and Prohibited Substances (National List) to address recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on November 5, 2009, and December 2, 2011. One recommendation addressed in this proposed rule pertains to amending the annotations for two exemptions (uses) for peracetic acid in organic crop production. Additional NOSB recommendations addressed in this proposed rule pertain to changing the annotations for three substances, potassium hydroxide, silicon dioxide, and beta-carotene extract color, which are currently allowed for use in organic handling. This proposed rule would also address the NOSB recommendation to remove the allowance on the National List for the use of nonorganic annatto extract color in organic handling.

DATES: Comments must be received by (INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER).

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2646-So., Ag Stop 0268, Washington, DC 20250-0268.

Instructions: All submissions received must include the docket number AMS-NOP-12-0016; NOP-12-07PR, and/or Regulatory Information Number (RIN) 0581-AD27 for this rulemaking. You should clearly indicate the topic and section number of this proposed rule to which your comment refers. You should clearly indicate whether you support the action being proposed for the substances in this proposed rule. You should clearly indicate the reason(s) for your position. You should also supply information on alternative management practices, where applicable, that support alternatives to the proposed action. You should also offer any recommended language change(s) that would be appropriate to your position. Please include relevant information and data to support your position (e.g. scientific, environmental, manufacturing, industry, impact information, etc.). Only relevant material supporting your position should be submitted. All comments received will be posted without change to <http://www.regulations.gov>.

AMS is particularly interested in comments that identify any formulated hydrogen peroxide products labeled for agricultural use that contain more than 5% peracetic acid and that may be impacted by this rulemaking action. AMS is also interested in comments that describe whether product reformulation will be necessary and the timeframe that will be needed to comply with the proposed amendment for silicon dioxide at section 205.605(b) and the proposed

removal of annatto extract color from section 206.606. Such comments will be considered to determine appropriate effective dates for these changes to the National List if codified through a final rule.

Document: For access to the document to read comments received or any related background documents, go to <http://www.regulations.gov>. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, Room 2646-South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Melissa Bailey, Ph.D., Director, Standards Division, Telephone: (202) 720-3252; Fax: (202) 205-7808.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established, within the National Organic Program (NOP) (7 CFR part 205), the National List regulations in sections 205.600 through 205.607. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501-6522), and USDA organic regulations, in section 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National

List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List.

Under the authority of the OFPA, the National List can be amended by the Secretary based on recommendations developed by the NOSB. Since established, AMS has published multiple amendments to the National List beginning on October 31, 2003 (68 FR 61987). AMS published the most recent amendment to the National List on September 27, 2012 (77 FR 59287).

This proposed rule would amend the National List to reflect one recommendation submitted to the Secretary by the NOSB on November 5, 2009, and four recommendations submitted to the Secretary by the NOSB on December 2, 2011. Based upon their evaluation of petitions submitted by industry participants, public comments, market surveillance, and review of technical reports and previous NOSB recommendations, the NOSB recommended that the Secretary revise the annotations for two listings for peracetic acid for organic crop production at section 205.601, revise the annotations for two substances (potassium hydroxide, and silicon dioxide) for organic processing at section 205.605(b), and revise the annotation for one substance (beta-carotene extract color) for organic processing at section 205.606. In addition, the NOSB recommended removing one substance (annatto extract color) for organic processing from section 205.606, which allows the nonorganic form to be used when the organic form is not commercially available. The exemptions for the use of each substance in organic crop production and handling were evaluated by the NOSB using the criteria specified in OFPA (7 U.S.C. 6517-6518).

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

Section 205.601 Synthetic substances allowed for use in organic crop production.

This proposed rule would amend subparagraphs (a)(6) and (i)(8) of section 205.601 by amending two annotations for the following substance:

Peracetic acid. Peracetic acid is a clear, colorless liquid. It is an oxidizing agent formed by a reaction of hydrogen peroxide with acetic acid in water. The reaction used to produce peracetic acid proceeds until equilibrium is reached, and all three species (i.e., peracetic acid, hydrogen peroxide, and acetic acid) are always simultaneously present in any formulated peracetic acid product. Peracetic acid is often used in the food industry as a sanitizer and disinfects by oxidizing the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores.¹

This proposed rule would implement a recommendation issued by the NOSB at its meeting on November 5, 2009, to amend two listings for peracetic acid in subparagraphs (a)(6) and (i)(8) in section 205.601 of the National List. This rule proposes an amendment to the annotation for peracetic acid to clarify that peracetic acid is also permitted with certain restrictions in hydrogen peroxide formulations. This change is necessary to align the USDA organic regulations with an updated labeling requirement of the Environmental Protection Agency (EPA). The EPA labeling requirement specifies that peracetic acid needs to be listed as an active ingredient in some products that were previously labeled with hydrogen peroxide as the sole active ingredient.

¹ Technical advisory panel report for peracetic acid. November 6, 2000. Available in Petitioned Substances Database under “P,” at the NOP Web site:
<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5067081&acct=nopgeninfo>.

Peracetic acid was first added to section 205.601 of the National List on November 3, 2003 (68 FR 61987). AMS added peracetic acid to the National List for use in disinfecting equipment, seed, and asexually propagated plant material and for use to control fire blight bacteria. In 2007, the NOSB reviewed these two listings for peracetic acid under the five-year sunset process required by OFPA and, consistent with the NOSB recommendation, AMS renewed both listings on November 3, 2008 (73 FR 59479). Following their renewal in 2008, these two listings for peracetic acid are scheduled to sunset from the National List on November 3, 2013.

On August 12, 2008, AMS received a petition from a manufacturer of sanitizer products requesting an amendment to the National List to expand the allowance for peracetic acid in organic crop production.² The petition to amend the annotations for peracetic acid in sections 205.601(a)(6) and 205.601(i)(8) was submitted in response to a change in the EPA labeling requirements for certain products registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136-136(y)). These products were previously labeled with hydrogen peroxide as the sole active ingredient. Some hydrogen peroxide labeled products also contain a small amount of peracetic acid. Peracetic acid is produced from the *in situ* reaction of acetic acid, an inert ingredient permitted under section 205.601(m) of the USDA organic regulations, with the active ingredient hydrogen peroxide. EPA now requires that these hydrogen peroxide products be relabeled to list both hydrogen peroxide and peracetic acid as active ingredients.

Under the USDA organic regulations, hydrogen peroxide is permitted for plant disease control in organic crop production (§ 205.601(i)(5)). However, the allowance for peracetic acid

² The petition was submitted by BioSafe Systems LLC, and is available on the NOP Web site at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5071775&acct=nopgeninfo>.

for plant disease control under the USDA organic regulations is limited to fire blight control (§ 205.601(i)(8)). Since EPA now requires that peracetic acid be listed as an active ingredient on the product label in some hydrogen peroxide formulations, certifying agents and material evaluation programs have had to limit the use of these products to that for fire blight control in organic crop production. In the course of their product review, certifying agents and material evaluation programs identify the active ingredients on the product label (i.e. both hydrogen peroxide and peracetic acid) and ensure that the producer's use aligns with the restrictive allowance for peracetic acid on the National List at section 205.601(i)(8).

At its November 2009 public meeting, the NOSB reviewed the petition and public comment and, in response to the petition, issued a recommendation to amend the restrictive annotation for both listings of peracetic acid.³ A second motion to list peracetic acid without any restrictive annotation under the USDA organic regulations did not receive the required two-thirds majority to pass.⁴

The NOSB indicated in its recommendation for peracetic acid that its intent was to amend the annotations for peracetic acid to continue the availability of certain hydrogen peroxide containing products that are now required by EPA to list peracetic acid as a second active ingredient on the label. The NOSB recommended that AMS amend the annotations for peracetic acid to limit the amount of peracetic acid to no more than 5% concentration in hydrogen peroxide products. Although the NOSB recommendation characterized the small amount of peracetic acid in hydrogen peroxide products as “formerly allowed as inert,” peracetic acid is not an inert ingredient under section 205.601(m) of the USDA organic regulations, since peracetic

³ Available on the NOP Web site at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5092050&acct=nosb>.

⁴ Available on the NOP Web site at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5092052&acct=nosb>.

acid was not classified as a List 4 inert ingredient under the former classification system used by EPA.⁵ Instead, the peracetic acid may have always been present in some products from the in situ reaction of acetic acid (a List 4 inert ingredient) with the active ingredient hydrogen peroxide.

At its December 2, 2011, public meeting, the NOSB recommended that the listings for peracetic acid in section 205.601 be renewed under the sunset process.⁶ The NOSB sunset recommendation noted that the 2009 NOSB recommendation to amend the listing for peracetic acid had not yet been implemented by AMS. Since both NOSB recommendations for peracetic acid are outstanding, AMS is proposing to implement the 2009 NOSB recommendation for peracetic acid through this proposed rule. AMS intends to complete rulemaking prior to the November 3, 2013, sunset date for both listings of peracetic acid in section 205.601 of the National List. The amended listings for peracetic acid in section 205.601 would then be subject to review again within five years of their amendment, in accordance with the OFPA provision for the sunset of National List substances (7 U.S.C. 6517(e)).

The proposed changes are necessary to ensure that some formulated products that were previously compliant with the USDA organic regulations will continue to be permitted for many applications currently in use by organic crop producers. Such applications are in addition to those for disinfection of equipment, seed, and asexually propagated planting material, and for control of fire blight. Implementing the NOSB recommendation continues the use of certain hydrogen peroxide products for plant diseases which would not otherwise be permitted if the

⁵ The former list of EPA List 4 inert ingredients is available at <http://www.epa.gov/opprd001/inerts/cascomplete.pdf>. This list was last updated in August 2004 and is no longer maintained by EPA.

⁶ The NOSB recommendation for peracetic acid for Sunset 2013 is available on the NOP Web site at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5097089>.

product has been relabeled in accordance with EPA requirements to list peracetic acid as an active ingredient.

If this proposed amendment is not adopted as final, some hydrogen peroxide products that contain small amounts (i.e., 5% or less) of peracetic acid will become prohibited under the USDA organic regulations for most applications. Once these products are labeled in accordance with new EPA labeling guidelines, these products will be subject to the more restrictive allowances for peracetic acid under the USDA organic regulations. AMS has not identified any formulated hydrogen peroxide products which are labeled for agricultural use and contain more than 5% peracetic acid as an active ingredient on the product label. Furthermore, under this proposed action, formulated peracetic acid products, including hydrogen peroxide products that contain more than 5% peracetic acid, would continue to be subject to the same restrictive annotations for peracetic acid under the USDA organic regulations. Formulated hydrogen peroxide products that do not contain peracetic acid are not impacted by this rulemaking.

The NOSB recommended the addition of the following text to the current annotations for the peracetic acid listings in section 205.601: “Permitted in hydrogen peroxide formulations at concentration of no more than 5%.” In this proposed rule, AMS is proposing a modification to the NOSB’s recommended text as follows (emphasis added): “Permitted in hydrogen peroxide formulations at concentration of no more than 5% as indicated on the pesticide product label.” This amendment is intended to clarify the point that the 5% concentration of peracetic acid should be verified in the formulated product itself, not after the product has been diluted according to label directions prior to its application.

AMS has reviewed and proposes to address the NOSB recommendations with the modification described. This proposed rule would amend subparagraphs (a)(6) and (i)(8) of

section 205.601 of the National List by adding the following text to the current annotations for peracetic acid: “Permitted in hydrogen peroxide formulations at concentration of no more than 5% as indicated on the pesticide product label.” If finalized, the listings for peracetic acid in section 205.601 would be subject to review within five years of their amendment, in accordance with the OFPA provision for the sunset of National List substances (7 U.S.C. 6517(e)).

AMS is particularly interested in comments that identify any impacted hydrogen peroxide products labeled for agricultural use that contain more than 5% peracetic acid.

Section 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”

This proposed rule would amend section 205.605(b) by changing an annotation to expand the use for the following substance:

Potassium hydroxide. Potassium hydroxide is a white, caustic solid which is highly absorbent to the point that it dissolves into solution. It is alkaline in solution and available in pellets, flakes, sticks, lumps and powder. Commercially, food grade potassium hydroxide is obtained from the electrolysis of potassium chloride solution in the presence of a porous diaphragm. According to the Food and Drug Administration (FDA), potassium hydroxide is generally recognized as safe (GRAS) when used as a formulation aid, a pH control agent, a processing aid or a stabilizer and thickener (21 CFR 184.1631). The FDA regulations further provide that substances generally regarded as safe in food may be used to wash or to assist in the peeling of fruits and vegetables (21 CFR 173.315).⁷ In the lye peeling of fruits and vegetables,

⁷ Technical Report on Potassium hydroxide. May 21, 2001. Available in Petitioned Substances Database, under “P,” at the NOP Web site: <http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase>.

potassium hydroxide works by weakening the glycolic bonds of pectin responsible for peel adhesion so that the peel can be removed by water spray and other mechanical methods.

An allowance for potassium hydroxide was codified on the National List on December 21, 2000 (65 FR 80548). The allowance permitted potassium hydroxide in organic processing but prohibited its use in lye peeling of fruits and vegetables.⁸ On November 3, 2003, AMS published a final rule which amended the annotation for potassium hydroxide to allow its use for peeling peaches during the Individually Quick Frozen (IQF) production process (68 FR 62215). AMS based this amendment on a 2001 NOSB recommendation to allow potassium hydroxide for IQF peaches. The NOSB recommendation stated that there were no commercially viable alternatives to lye peeling of peaches. The NOSB also concluded that the low pH of the peaches would help neutralize the pH of the wastewater from organic processing and, therefore, mitigate any potentially adverse environmental effects of the potassium hydroxide use.

On April 19, 2011, AMS received a petition requesting that potassium hydroxide be permitted as a processing aid in the lye peeling of fresh peaches for canning.⁹ The petition explained that the peeling processes for freezing or canning peaches are identical. Therefore, the petition claimed that an allowance to use potassium hydroxide to peel peaches for canning is consistent with the existing allowance for the use of potassium hydroxide in peeling of organic peaches for frozen products. The petition also stated that no other treatment or process is equivalent to potassium hydroxide for peeling peaches, in terms of minimal loss of texture, flavor, appearance and aroma.

⁸ In 1995, the NOSB recommended the addition of potassium hydroxide to section 205.605 for use in organic processing with an annotation prohibiting its use in the lye peeling of fruits and vegetables. The NOSB based the restriction on concerns about the environmental effects of the waste products of the lye peeling process, and their understanding that mechanical and non-chemical alternatives were available for peeling most fruits and vegetables.

⁹ The petition was submitted by Pacific Coast Producers, and is available in the Petitioned Substances Database, under “P,” at the NOP Web site: <http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase>.

At its November 29 – December 2, 2011 meeting, the NOSB considered the petition to amend the annotation for potassium hydroxide to allow its use in lye peeling of peaches to be canned. In its deliberations, the NOSB noted a lack of commercially viable alternatives for peeling peaches and stated that the acidity of the fruit and on-site buffering would mitigate any potential environmental impact of alkaline waste from a peach processing facility using potassium hydroxide. The NOSB also reasoned that freezing and canning are the primary commercial processes for peaches and that these processes are identical until the last step. Based upon the information in the petition and technical report, and prior NOSB action regarding potassium hydroxide, the NOSB recommended that potassium hydroxide be allowed for any peach peeling in organic processing, rather than limiting the allowance to peaches to be frozen using the IQF process.

AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend the listing for potassium hydroxide in section 205.605(b) by deleting the words, “during the Individually Quick Frozen (IQF) production process”. This change would, in effect, allow the use of potassium hydroxide in lye peeling of peaches for all types of organic peach processing, including canning and the IQF process. If finalized, the listing for potassium hydroxide in section 205.605(b) would be subject to review within five years of its amendment, in accordance with the OFPA provision for the sunset of National List substances (7 U.S.C. 6517(e)).

This proposed rule would further amend section 205.605(b) by adding an annotation to specify the permitted use of the following substance:

Silicon dioxide. Silicon dioxide is currently listed as an allowed synthetic in organic processing in section 205.605(b). In accordance with applicable FDA requirements for its use as

a food additive¹⁰, the substance can serve many technical functions including as an anti-caking agent, a defoamer, a stabilizer, or an adjuvant.

At its meeting November 29 – December 2, 2011, the NOSB considered a petition requesting the removal of silicon dioxide from section 205.605(b) of the National List. The petition was submitted by a manufacturer of an organic product derived from rice hulls. The petitioner stated that the rice hull product is an organic alternative for the use of synthetic silicon dioxide in some applications. The petitioner requested that silicon dioxide be removed from the National List based on the criteria provided under section 205.600(b)(1) of the USDA organic regulations. Section 205.600(b)(1) specifies that any synthetic substance used as a processing aid or adjuvant on the National List must be evaluated under the criteria that the substance cannot be produced from a natural source and there are no organic substitutes.

During its deliberations, the NOSB stated that the alternative organic product, derived from organic rice hulls, could be a replacement for silicon dioxide in some, but not all, current applications of silicon dioxide in organic handling. Specifically, the NOSB noted that the alternative organic product does not function as a replacement for synthetic silicon dioxide as a defoamer. In addition, the NOSB also noted that there may be other applications where the continued use of silicon dioxide may be necessary if the alternative organic product does not provide the functionality needed.

In order to recognize the availability of the alternative organic product as a substitute for some uses of silicon dioxide, the NOSB recommended that an annotation be added to the listing

¹⁰ There are multiple references in the FDA regulations that are relevant to silicon dioxide and its authorized use in food for human consumption. These are cited in the Technical Report prepared for the NOSB and include 21 CFR 172.480, 21 CFR 172.230, 21 CFR 73.340, 21 CFR 160.105, 21 CFR 160.185, and 21 CFR 182.90. See Technical Report on Silicon Dioxide. November 12, 2010. Available in Petitioned Substances Database, under “S,” at the NOP Web site: <http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase>.

for silicon dioxide at section 205.605(b) as follows: “Silicon dioxide – allowed for use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available.”

AMS understands that the intent of the NOSB’s recommendation is to allow the continued use of silicon dioxide as a defoamer and to require the use of a nonsynthetic substance instead of silicon dioxide when possible. To ensure clarity and consistency within the USDA organic regulations, AMS is proposing a modification to the NOSB’s recommendation by proposing an annotation which would read as follows: “Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.”

AMS is proposing this modification to specify the specific alternative substance (i.e., organic rice hulls) that the NOSB considered during its review, rather than including the general term “nonsynthetic alternatives.” AMS has specified the particular nonsynthetic alternative within the annotation so that certifying agents can consistently verify that organic handlers are in compliance with the regulations. The clarification also reduces the burden on organic handlers since they would not be required to demonstrate that all nonsynthetic inputs were considered prior to the use of silicon dioxide.

AMS has also specified in the annotation that the rice hulls must be organic, since the use of conventional (i.e., nonorganic) rice and rice products is not permitted in products labeled as “organic” under the USDA organic regulations. Section 205.606 of the National List specifies the nonorganically produced agricultural products that may be used as ingredients in or on processed products labeled as “organic.” Substances included in section 205.606 are only permitted when the product is not commercially available in organic form. Rice and rice hulls are not included at section 205.606 of the National List; therefore, the use of nonorganic rice

products would not be permitted in products labeled as “organic.” This proposed rule does not change this requirement. Because section 205.606 does not apply to products labeled “made with organic (specified ingredients or food group(s)),” organic or nonorganic rice hulls would be permitted as a substitute for silicon dioxide in the 30 percent nonorganic content of a “made with organic (specified ingredients or food group(s)),” product under section 205.301(c) of the USDA organic regulations.

AMS understands that the NOSB recommendation intended for silicon dioxide to continue to be allowed in applications when organic rice hulls do not adequately substitute for the functionality provided by silicon dioxide. Commercially available is defined under section 205.2 of the USDA organic regulations as “the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.” Linking the use of silicon dioxide by annotation to the commercial availability of organic rice hulls reflects the NOSB’s intent to permit the use of synthetic silicon dioxide when organic rice hulls do not fulfill an essential function in a system of organic handling, as determined by the certifying agent in the course of reviewing the organic plan. A difference in cost between synthetic silicon dioxide and organic rice hulls would not be considered a permitted justification for use of synthetic silicon dioxide under the proposed annotation.

AMS has reviewed and proposes to address the NOSB recommendation with the modification described. This proposed rule would amend section 205.605(b) by adding an annotation for silicon dioxide to read as follows: “Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.” AMS is seeking comments that describe whether product reformulation will be necessary and the timeframe that

will be needed to comply with this change. Such comments will inform an appropriate effective date for this amendment if finalized. If finalized, the listing for silicon dioxide in section 205.605 would be subject to review within five years of its amendment, in accordance with the OFPA provision for the sunset of National List substances (7 U.S.C. 6517(e)).

Section 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

This proposed rule would amend subparagraph (d)(3), redesignated under this proposed action as (d)(2), of section 205.606 by changing the annotation to correct the Chemical Abstracts Service (CAS) number and to allow an additional source of the following substance:

Beta-carotene extract color. Beta-carotene is a carotenoid. Carotenoids are natural pigments synthesized by plants that aid in photosynthesis by absorbing light and protect the plant from photosensitization. Carotenoids commonly exhibit antioxidant activity in food. In the human body, beta-carotene is converted to vitamin A. Beta-carotene is the most common carotenoid and the major colorant in carrot and palm oil seed extracts and is also found in cantaloupes, apricots, sweet potatoes and other orange, red and dark green fruits and vegetables.¹¹

Beta-carotene can be produced through various methods including chemical synthesis, fermentation of microorganisms (fungi, yeasts, or bacteria), and extraction from certain algae (*Dunnaliella salina*) and vegetables. Obtaining beta-carotene from natural sources generally involves propagation and harvest of the source and solvent extraction of the beta-carotene. According to the 2011 Technical Report for beta-carotene, only one preparation of crystalline

¹¹ Technical Report on Beta-carotene extract color. July 15, 2011. Available in Petitioned Substances Database, under “C” for colors, at the NOP Web site: <http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase>.

beta-carotene from carrots is commercially available and the substance is not yet obtained commercially from other vegetable sources.

Beta-carotene is used as a color additive and as a nutritive supplement in a variety of foods including dairy products, fats and oils, and processed fruits and fruit juices. As a colorant, it adds a deep orange to light yellow color to the food depending upon the concentration. The FDA regulations provide that beta-carotene, prepared synthetically or obtained from natural sources, may be safely used for coloring foods in amounts consistent with good manufacturing practices. It may not be used in foods for which there is an FDA standard of identity unless that standard of identity authorizes its use (21 CFR 73.95).

On June 27, 2007, a listing for beta-carotene extract color, derived from carrots, was added to section 205.606 of the National List through an interim final rule (72 FR 35137).¹² This allowance provides for the use of the nonorganic form of beta-carotene extract color, derived from carrots, in organic processing when an organic form is not commercially available.¹³

On July 20, 2009, AMS received a petition to amend the annotation for beta-carotene extract color derived from carrots.¹⁴ The petition requested two changes to the listing for beta-carotene extract color: (i) correction of the CAS number; and (ii) the inclusion of algae as a source of beta-carotene extract color. The petition indicated that the CAS number listed for beta-carotene extract color (CAS # 1393-63-1) is incorrect and refers to the pigment found in annatto

¹² The interim final rule was superseded by a final rule published June 6, 2012 (77 FR 33290) which renewed the listing for beta-carotene extract color as part of the 2012 sunset review. The final rule was effective June 27, 2012.

¹³ In April 2007, the NOSB recommended adding beta-carotene color extract derived from carrots to 205.606. The NOSB concluded that this substance was not available in organic form because the specific varieties of carrots grown for beta-carotene production were not produced organically in sufficient quantities. NOSB Formal Recommendation on Beta-carotene color derived from carrots. April 21, 2007. Available at the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5061991>.

¹⁴ The petition was submitted by D.D. Williamson & Co., Inc., and is available from the NOP Web site in the Petitioned Substances Database: <http://www.ams.usda.gov/NOPPetitionedSubstancesDatabase>. A separate petition has been submitted by the International Formula Council for the use of the synthetic form of beta-carotene in organic processing.

extract color. The petition also stated that algae provide the only source of beta-carotene that can be produced with allowed solvents, such as nonsynthetic ethanol, vegetable oil, and carbon dioxide.

At its November 29 – December 2, 2011 meeting, the NOSB considered the petition to amend the listing for beta-carotene extract color. In its deliberations, the NOSB considered its October 2010 recommendation to prohibit the use of synthetic solvents and carrier systems or any artificial preservative in the production of colors used in organic processing. The October 2010 NOSB recommendation specified that the listing for colors derived from agricultural products at section 205.606 should include the following annotation: “Must not be produced using synthetic solvents and carrier systems or any artificial preservative.”¹⁵ This NOSB recommendation was codified through a final rule published on June 6, 2012 (77 FR 33290). The NOSB accepted the petition’s justification for revision of the listing for beta-carotene extract color, which stated that the only method to extract beta-carotene from carrots uses synthetic solvents and would not comply with the revised requirements for colors derived from agricultural products in section 205.606. The NOSB concluded that the production of beta-carotene color from algae, as described in the petition, could comply with the amended annotation for colors in section 205.606 and be an acceptable source of beta-carotene extract color in organic products when an organic form was not commercially available. The NOSB also recommended that the CAS number be corrected to 7235-40-7 for this listing.¹⁶

AMS has reviewed and proposes to address the NOSB recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend

¹⁵ NOSB Formal Recommendation on Colors derived from agricultural ingredients. October 2010. Available at the NOP Web site: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088018&acct=nosb>.

¹⁶ NOSB Formal Recommendation on Annatto Extract Color. December 2, 2011. Available at the NOP Web site: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5097101>.

paragraph (d)(3), redesignated under this action as paragraph (d)(2), of section 205.606 of the National List by: (i) replacing the text, “(CAS # 1393-63-1)” with the text “(pigment CAS # 7235-40-7)”; and (ii) adding the words, “or algae” between “carrots” and “(pigment CAS # 7235-40-7).” If finalized, the listing for beta-carotene extract color at section 205.606 would be subject to review within five years of its amendment, in accordance with the OFPA provision for the sunset of National List substances (7 U.S.C. 6517(e)).

This proposed rule would further amend paragraph (d) of section 205.606 by removing the exemption for the following substance:

Annatto extract color. Annatto extract color is made from the dried seed of Bixa orellana L., an evergreen shrub native to Central and tropical South America, which is cultivated globally in tropical areas. The seed’s coating contains carotenoid pigments, principally bixin, which are used to impart a deep orange to light yellow color, depending upon the concentration, to foods and beverages. The water soluble form is used as a colorant in foods, such as hard cheeses, bakery products, sauces, and sugar and flour confectionary. This form is available spray-dried on a carrier or is available in an aqueous solution. The oil soluble form is used in foods with a high fat content, such as salad dressings. This form is available dried or suspended in vegetable oil.¹⁷ Organic annatto extract seeds are hulled, crushed into small pieces and physically ground together in vegetable oil or mildly alkaline water. The oil and water are filtered and concentrated, and retain the pigments contained in the seed.

According to FDA, annatto extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practices, except where a standard of identity does not authorize its use. The FDA has also determined that annatto extract color is exempt from

¹⁷ Food and Agriculture Organization of the United Nations. 1995. Non-Wood Forest Products, Natural Colourants and Dyestuffs, <http://www.fao.org/docrep/v8879e/V8879e00.htm>

color certification (21 CFR 73.30). Under section 721(c) of the Federal Food, Drug and Cosmetic Act (FFDCA), the FDA exempts certain color additives from certification if FDA approval is not necessary for the protection of the public health.

On June 27, 2007, a listing for annatto extract color (pigment CAS # 1393-63-1), water and oil soluble, was added in section 205.606 of the National List through an interim final rule (72 FR 35137).¹⁸ This allowance provides for the use of the nonorganic forms of water and oil soluble annatto extract color in organic processing when an organic form is not commercially available. The 2007 rule stated that the global supply production of annatto seeds was insufficient to consistently provide organic sources of this substance.

In September 2010, AMS received a petition for the removal of annatto extract color from the National List.¹⁹ The petition stated that the use of nonorganic annatto extract in organic processing was no longer warranted because there is an adequate supply of organic annatto seed from which organic annatto extract can be produced. The petition explained that the geographic diversity in organic annatto seed production protects the supply from interruptions due to weather. In addition, the petition indicated that the availability of water soluble, oil soluble, oil soluble suspensions and powdered forms of annatto extract are adequate for the needs of the organic industry.

On June 6, 2012, AMS published a final rule, renewing the listing for annatto extract color at section 205.606, prior to its sunset date on June 27, 2012 (77 FR 33290). The final rule is consistent with the October 2010 NOSB sunset recommendation to continue the allowance for the use of nonorganic annatto extract color. In the justification for recommending renewal in

¹⁸ The interim final rule was superseded by a final rule published June 6, 2012 (77 FR 33290) which renewed the listing for annatto extract color as part of the 2012 sunset review. The final rule was effective June 27, 2012.

¹⁹ The petition was submitted by D.D. Williamson & Co., Inc. and is available from the NOP Web site in the Petitioned Substances Database under “C” for colors: <http://www.ams.usda.gov/NOPPpetitionedSubstancesDatabase>.

2010, the NOSB explained its uncertainty about the commercial availability of organic powdered annatto extract based upon public comment at that time. The NOSB indicated that it would address the commercially availability of liquid and dry forms of annatto extract color during its future consideration of the September 2010 petition to remove annatto extract color from the National List.²⁰

At the November 29 – December 2, 2011 NOSB meeting, the NOSB considered the September 2010 petition to remove annatto extract from the National List. The NOSB Handling Committee conducted market research to verify that the forms of annatto extract used by organic handlers are available organically. Their findings indicated that liquid forms of organic annatto extract were widely available, and the powdered form of organic annatto extract was available, but not widely used. The NOSB Handling Committee proposed that the annotation for annatto extract be revised from water and oil soluble to liquid and powdered forms to reflect the forms found in the marketplace. To ensure that the NOSB considered all forms of annatto extract needed by organic handlers, the Committee solicited public comment on any specific needs for a continued allowance of nonorganic annatto extract.²¹ During the November 29 – December 2, 2011, NOSB meeting, the Handling Committee explained that it had not received public comment indicating that nonorganic forms of annatto extract were needed. Therefore, the NOSB approved a recommendation to remove annatto extract color from section 205.606(d).²²

AMS has reviewed and proposes to address the NOSB's recommendation through this proposed rule. Consistent with the NOSB recommendation, this proposed rule would amend

²⁰ NOSB Formal Recommendation: Colors derived from agricultural products – Annotation Change. October 28, 2010. Available at the NOP Web site:

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088018&acct=nosb>.

²¹ NOSB Handling Committee recommendation on Annatto extract color. September 29, 2011. Available at the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5094391>.

²² NOSB Formal recommendation on Annatto extract color, December 2, 2011. Available at the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5097099>.

paragraph (d) of section 205.606 by removing annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble and redesignating paragraphs (d)(2) through (d)(19) as paragraphs (d)(1) through (d)(18). AMS is seeking comments that describe whether product reformulation will be necessary and the timeframe that will be needed to comply with this change. Such comments will inform an appropriate effective date for this amendment if finalized.

III. Related Documents

Two notices were published regarding meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following Federal Register notices: (1) 74 FR 46411, September 9, 2009 (peracetic acid); and (2) 76 FR 62336, October 17, 2011 (potassium hydroxide, silicon dioxide, beta-carotene extract color, and annatto extract color).

IV. Statutory and Regulatory Authority

The OFPA, as amended, (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under section 205.607 of the USDA organic regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at <http://www.ams.usda.gov/AMSV1.0/nop>.

A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in the OFPA (7 U.S.C. 6514(b)). States are also preempted by the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to the OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C.

1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the FFDCA (21 U.S.C. 301-399), nor the authority of the Administrator of EPA under the FIFRA (7 U.S.C. 136-136(y)).

The OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's final decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

U.S. sales of organic food and non-food have grown from \$1 billion in 1990 to \$31.4 billion in 2011. Sales in 2011 represented 9.5 percent growth over 2010 sales.²³ According to USDA, National Agricultural Statistics Service (NASS), certified organic acreage exceeded 3.5 million acres in 2011.²⁴ According to NOP's Accreditation and International Activities Division, the number of certified organic operations in the U.S. has more than doubled over time from approximately 7,000 operations in 2000 to over 17,000 operations by the end of 2011. Of these operations, over 4,900 are organic handlers, over 10,000 are organic crop producers, and over 1,900 are organic livestock producers. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

In addition, the USDA has 87 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA. Certifying agents reported approximately 29,000 certified operations worldwide in 2011.

AMS has considered the economic impact of this action on small entities. The effect of this proposed rule would be to expand the allowed uses of peracetic acid in organic crop production. AMS concludes that expanding the allowance for peracetic acid on the National List both addresses EPA relabeling issues for products used in organic crop production and continues access to a substance used for plant disease control on organic farms. Therefore, this action will be beneficial to small agricultural service firms. This proposed rule also would expand the use

²³ Organic Trade Association. 2012. Organic Industry Survey. www.ota.com.

²⁴ U.S. Department of Agriculture, National Agricultural Statistics Service. October 2012. 2011 Certified Organic Productions Survey. <http://usda01.library.cornell.edu/usda/current/OrganicProduction/OrganicProduction-10-04-2012.pdf>.

of potassium hydroxide and beta-carotene extract color in organic handling. AMS concludes that expanding the allowance for these substances on the National List provides organic handlers with more tools for processing organic products and, therefore, will be beneficial to small agricultural service firms. This proposed rule would amend the allowance for synthetic silicon dioxide such that organic rice hulls would be required as an alternative to silicon dioxide when commercially available. The proposal would continue to allow the use of silicon dioxide as a defoamer and would allow the use of silicon dioxide when organic rice hulls are not available in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic handling. This flexibility is intended to minimize the impact on small entities. This proposed rule would also remove the allowance for one nonorganic agricultural substance, annatto extract, in organic handling. The NOSB has determined that annatto extract is commercially available in organic form in sufficient quantities for organic handling. AMS concludes that the economic impact of this amendment to the National List, if any, would be minimal to small agricultural service firms and may spur further development of organic annatto production. Accordingly, AMS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, and Chapter 35.

E. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review

reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. General Notice of Public Rulemaking

This proposed rule addresses recommendations submitted to the Secretary by the NOSB for substances on the National List of Allowed and Prohibited Substances. A 30-day period for interested persons to comment on this rule is provided. Thirty days is deemed appropriate because potential changes to these listings were widely publicized through two NOSB meetings. Further, certain proposed amendments, one for potassium hydroxide in organic handling, and those for peracetic acid in organic crop production, are considered time sensitive and critical to organic production. The proposed amendment to the listing for potassium hydroxide would provide more tools for organic peach processors by allowing use of this substance to peel peaches for canning, in addition to its current allowance to peel peaches for frozen products. The proposed amendments to the listings for peracetic acid would ensure consistency with EPA labeling requirements for hydrogen peroxide products containing peracetic acid.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is proposed to be amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501 – 6522.

2. Section 205.601 is amended by revising paragraphs (a)(6) and (i)(8) to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(a) * * *

(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Permitted in hydrogen peroxide formulations at concentration of no more than 5% as indicated on the pesticide product label.

* * * * *

(i) * * *

(8) Peracetic acid—for use to control fire blight bacteria. Permitted in hydrogen peroxide formulations at concentration of no more than 5% as indicated on the pesticide product label.

* * * * *

3. In § 205.605 paragraph (b), revise the entry for “Potassium hydroxide” and “Silicon dioxide” to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

* * * * *

(b) * * *

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

* * * * *

Silicon dioxide—Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

* * * * *

4. Section 205.606 is amended by:

A. Removing paragraph (d)(1);

B. Redesignating (d)(2) through (d)(19) as (d)(1) through (d)(18); and

C. Revising paragraph (d)(2) to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

* * * * *

(d) * * *

(2) Beta-carotene extract color—derived from carrots or algae (pigment CAS# 7235-40-7).

* * * * *

Dated: January 30, 2013

Rex A. Barnes
Acting Administrator
Agricultural Marketing Service

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